SLOVENSKI STANDARD
SIST EN 13485:2024

01-februar-2024

Termometri za merjenje temperature okolice ali notranje temperature pri prevozu, skladiščenju in distribuciji toplotno občutljivega blaga - Preskusi, značilnosti, ustreznost

Thermometers for measuring the ambient or internal temperature for the transport, storage and distribution of temperature sensitive goods - Tests, performance, suitability

Thermometer zur Messung der Umgebungs- und Innentemperatur für den Transport, die Lagerung und die Verteilung von temperaturempfindlichen Produkten - Prüfung, Leistung, Gebrauchstauglichkeit

Thermomètres de mesure de la température ambiante ou interne pour le transport, le stockage et la distribution des marchandises thermosensibles - Essais, performance, aptitude à l'emploi

Ta slovenski standard je istoveten z: **EN 13485:2023**

ICS:

17.200.20	Instrumenti za merjenje temperature	Temperature-measuring instruments
67.260	Tovarne in oprema za živilsko industrijo	Plants and equipment for the food industry

SIST EN 13485:2024 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 13485

December 2023

ICS 17.200.20; 67.260

Supersedes EN 13485:2001

English Version

Thermometers for measuring the ambient or internal temperature for the transport, storage and distribution of temperature sensitive goods - Tests, performance, suitability

Thermomètres de mesure de la température ambiante ou interne pour le transport, le stockage et la distribution des marchandises thermosensibles - Essais, performance, aptitude à l'emploi

Thermometer zur Messung der Umgebungs- und Innentemperatur für den Transport, die Lagerung und die Verteilung von temperaturempfindlichen Produkten - Prüfung, Leistung, Gebrauchstauglichkeit

This European Standard was approved by CEN on 20 November 2023.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN 13485:2023) has been prepared by Technical Committee CEN/TC 423 “Means of measuring and/or recording temperature in the cold chain”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2024, and conflicting national standards shall be withdrawn at the latest by June 2024.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 13485:2001.

EN 13485:2023 includes the following significant technical changes with respect to EN 13485:2001:

a) clarification of the scope;

b) complete revision of Clause 4;

c) addition of class 0,2 to the document;

d) revision of 5.1;

e) revision of 5.3 with examples to clarify the process;

f) revision of 5.5.1 and 5.5.3;

g) update of Clauses 7 and 8 according to the revised clauses;

h) revision of Clause 9;

i) addition of Annex B regarding expected operation time and storage capacity;

j) addition of Annex C regarding examples for temperature conditions;

k) addition of Annex D regarding example of a life cycle sheet;

l) addition of Annex E as guideline to the verification process;

m) addition of Annex F as guideline to determine the expanded uncertainty.

This document meets the objectives of the following directives:

— 92/1/EEC of January 15, 1992 of the Commission of the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption; (Commission Regulation (EC) No 37/2005 of 12 January 2005 on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption with EEA relevance);

— 92/2/EEC of January 13, 1992 of the Commission laying down the sampling procedure and the community method of analysis for the official control of the temperatures of quick-frozen foods intended for human consumption;

— 93/43/EEC of June 14, 1993 of the Council of the hygiene of foodstuffs and in particular on “temperature control criteria” (Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs).

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

1 Scope

This document specifies the technical and functional characteristics for all types of thermometers (electronic, mechanical, etc.) for equipping the means used for the transport, storage and distribution of temperature sensitive goods and for measuring the ambient or internal temperature of the products between −80 °C and +85 °C.

It specifies the test methods which allow the verification of the equipment's conformity to suitability and performance requirements.

It applies to the whole thermometer and indicating device(s). The temperature sensor(s) can be integrated into the thermometer or remote from it (wired or wireless external temperature sensor(s)).

It does not specify the location of the thermometer and its sensors with respect to types of usage such as transport, storage and distribution.

NOTE Examples for the transport, storage and distribution of temperature sensitive goods between −80 °C and +85 °C include chilled, frozen, deep frozen and quick-frozen food; ice cream; fresh and hot food; pharmaceuticals; blood and organs; chemicals; biologicals; electronic and mechanical devices; flowers, plants and bulbs; raw materials and liquids; animals; art and furnishings.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 13486, *Temperature recorders and thermometers for measuring the ambient or internal temperature for the transport, storage and distribution of temperature sensitive goods — Periodic verification*

EN 60068-2-27, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

EN 61010-1, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements*

EN IEC 61000-6-2, *Electromagnetic compatibility (EMC) — Part 6-2: Generic standards — Immunity for industrial environments*

EN IEC 61000-6-3, *Electromagnetic compatibility (EMC) — Part 6-3: Generic standards — Emission standard for residential, commercial and light-industrial environments*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

JCGM 200:2012, *International Vocabulary of Metrology — Basic and general concepts and associated terms (VIM)*[1]

[1] Available at: https://www.bipm.org/en/committees/jc/jcgm/publications

3 Terms and definitions

For the purposes of this document, the terms and definitions given in the VIM (JCGM 200:2012) and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp/

— IEC Electropedia: available at https://www.electropedia.org/

3.1
measurement
set of operations having the object of determining a value of a quantity

3.2
thermometer
any device to measure and display temperature

3.3
temperature sensor
element of a measuring instrument or measuring chain that is directly affected by the temperature

3.4
external temperature sensor
sensor which measures a temperature independent of the enclosure of the indicating device

3.5
internal temperature sensor
sensor which measures the temperature of the enclosure of the thermometer

3.6
storage and transport conditions
extreme conditions which a non-operational measuring instrument can withstand without damage and without degradation of specified metrological characteristics when it is subsequently operated under its rated operating conditions

3.7
chilled food
food which has been subjected to cooling (without freezing) and is intended to be maintained at low temperature

3.8
frozen food
food which has been subjected to a freezing process specially designed to preserve the wholesomeness and quality of the product

3.9
deep-frozen or quick-frozen food
food which has been subjected to a quick-freezing or deep-freezing process

3.10
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The activities carried out for verification are sometimes called a qualification process.

Note 3 to entry: The word “verified” is used to designate the corresponding status.

[SOURCE: EN ISO 9000:2015, 3.8.12]

4 Requirements

4.1 General

Manufacturers shall make recommendations on the specification of ancillary equipment in order to meet the performance requirements of this document.

The manufacturer shall specify the use of the transport, storage and operational conditions. Examples are given in the informative Annex A and Tables C.1 and C.2 in Annex C.

NOTE Further information is included in EN IEC 60721-3-3 and EN 60721-2-3.

Manufacturers shall state the intended use and requirements of their applications. Examples are given in Annex B.

If the system would have the possibilities to prevent and/or detect manipulation and to prove the validity of the data, it can be validated according to the relevant chapters in EN 12830.

4.2 Measuring range

— The temperature sensor shall be able to measure the air and/or product temperature in the measuring range that it is specified by the manufacturer;

— The thermometers shall be able to indicate the air and/or product temperature which is extended twice the maximum permissible error for the maximum specified class of the temperature sensor stated by the manufacturer in both directions, see 4.8.2;

EXAMPLE Measuring range −20 °C till +90 °C, accuracy 0,5. The indication range is at least from −21,0 °C to +91,0 °C.

4.3 Locking of settings

The means for adjusting settings of the thermometer shall either:

— be protected against accidental or unauthorised modifications; and/or

— record each adjustment of any settings that remain accessible.

4.4 Load indicator

For devices with an autonomous power supply, this shall be indicated on the thermometers or on the power supply or in the technical documentation, with the corresponding usage temperature.

The manufacturer shall install an indicating device, warning light or message on the device or remote, warning the user that the power source needs replacing.

The manufacturer shall avoid any measurement when the charge of the battery is too low.

The manufacturer shall declare operational limitations as indicated in Annex B.